Curriculum Vitae – Work experience.

Name:	**Lone Cleveland Andersen**
Birth:	15. September 1962
Nationality:	Danish
Education/year:	M.Sc. Pharm., 1993
Education inst.:	The Danish Pharmaceutical University, Copenhagen
CV updated:	08-FEB-2022

CURRENT CARRIER.
Since July 2014 foundation of own Consultancy Company; **GxP-Pharma Support AS.**
Professional Background: Pharmacist with +28 years profound experience in pharmaceutical and biopharmaceutical productions within EU/US GxP regulations:
Seven years in GxP-Pharma Support AS; Senior QA- & GxP-specialist within GMP, GDP, GVP and ISO 17025.
Seven years in The Danish Medicines Agency and in the EMA as GMP/GDP/GVP Medicines Inspector and inspector of Blood Banks. Auditor for internal ISO audit according to DS/EN ISO 17025 (laboratory standard) and DS/EN ISO 17020 (inspection standard).
Thirteen years in different Novo Nordisk Production Sites in Denmark and worldwide as Project Manager for establishment of licence and contract manufacturers worldwide. LEAN coordinator for implementing LEAN tools in the organisation and teach LEAN principles. Head of a professional quality group handling quality defects. GMP coordinator for packaging and aseptic productions and production of API Insulin. Manager for aseptic cleaning team and environmental assistant.

August 2014 – present, founder and CEO of GxP-Pharma Support A/S:
Senior QA- & GxP Specialist

<u>QA consultancy / QP responsibility (long term assignments):</u>

- Acting as Qualified Person according to DK and EU GMP legislation and EU Directives:
  - <u>QP at Scanpharm AS</u> from Jan. 2020 to Nov. 2021, QP for solid dosage forms, liquids and granules in bulk; release of medicinal products and intermediates. Daily QA support e.g. deviation and CAPA management, change management, SOP writing and approval, approval of specifications, batch documentation, validation/re-validation and qualifications, Risk Assessments, plan, execute self-inspections, prepare and conduct GMP/GDP training, GMP compliance manager, implement quality awareness. Project manager for ensuring sufficient compliance in order to re-gain a suspended GMP license under compliance monitoring by the DKMA. Participating in compliance meetings with the DKMA and prepare and assist during 3 DKMA inspections within 1,5 year (April + Nov. 2020, Nov. 2021). Further assignments at Scanpharm: Responsible Person, Pharmacovigilance responsible and interim QA Manager since May 2020.
  - <u>Interim QA Manager at Scanpharm AS</u> from May 2020 to Nov. 2021; managing the QA department with 4 employees, optimize and structure QA workflows/processes, implement a sufficient quality level and increase quality mind-set. Engaged in QMR process and host for 3 DKMA inspections. Part of the management group and participate in management meetings.

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- QP at Viminco AS from May 2019 to end December 2019; QP for solid dosage forms e.g. release of medicinal products. Daily QA support e.g. deviation and CAPA management, approve training documentation, change management, write and approve technical and QA agreements, Supply Chain Traceability (SCT), support stability chambers and expansion of warehouse and new stability chambers, approve temperature mapping, risk assessments, SOP writing and approval, approval of specifications, masters, batch documentation and external audit reports. Quality Oversight for release process, approve development protocols/reports (solid dosage forms and analysis), equipment qualifications, URS, validations, customer complaints handling, approve QC specifications and OOS.

- QP at LEMAN AS from November 2016 to September 2017, QP for a transport company due to storage of biological and sterile API. Establishment and implementation of a new GMP Quality Management System built in a GDP QMS, train staff in GMP and quality awareness. Prepare for GMP approval inspection by the DKMA. Daily deviation and CAPA management, change management, risk assessments, support to IT systems, SOP writing and approval. Prepare and participate in customer audits and authorities inspections.

- QP at Veloxis Pharmaceuticals; from March 2015 to November 2016; delegated QP and QA support (and QP from February 2016 to November 2016) for solid dosage forms manufactured and packed by EU CMO's. Deviations, CAPA and change management, customer complaints handling write and approve technical and QA agreements, GMP training , risk assessments, SOP writing and approval, approval of specifications, masters, batch documentation, conduct self-inspections in QA department, Clinical trials department, logistics/technical department and Mock-recall audit. QP-QP agreements and TC with CMO QP's. Prepare for and participate in routine inspections from the DKMA. Audit of CMO's; solid dosage forms, chemical and microbiological laboratory and audit of chemical API manufactures in India and Taiwan, audit of pharmacovigilance partner. Close down the Danish site.

Other long term QA support

- Plesner Layers; from July 2021 (and on-going), Senior QA- and GxP Specialist in GMP, supporting with profound knowledge of DK, EU/US GxP legislation; clarify questions and participate in court meetings.

- Symphogen AS from May 2016 to end of December 2018, QA support to IMP manufactured by CMO's. Technical transfer of analytical methods, technical transfer of manufacturing processes (antibody and biotech products), approval of specifications, master batch records, process validation, cleaning validation, validation/qualification of equipment, write and approve SOP's, approve protocol/reports of stability studies, risk assessment, compliance checks, change controls, deviation and CAPA management, TSE/BSE certificates, Shelf-life statements, update of GXP documents, general troubleshooting, planning and conduction self-inspections in QA, IT, IMP laboratories and support functions, audit of CMO's and External Warehouse partner, write and approve Technical- and QA agreements, compliance checks and prepare for a planned

GMP approval inspection.

- Nomeco AS from August 2014 to July 2016; Daily QA support e.g. deviation and CAPA management, approve training documentation, change management, conduct GDP and GMP training, support to narcotics licence, audit of Eservice providers e.g. cleaning company, security company, archive facility, write and approve QA agreements, temperature mapping of storage facilities, self-inspections, SOP writing and approval, approval of specifications, masters, batch documentation and external audit reports, participate in customers audits.

GDP support, Responsible person

- AP Services ApS; from December 2020 (and on-going), consultant for RP by establish a complete QMS according to DK/EU GDP legislation for a new Wholesaler distributing medicinal products to WHO, UNHCR etc. Train Staff in basic GDP and participate in re-inspection from the DKMA for a final approval. Execute continuous GDP consultancy.

- Daiichi Sankyo Nordics Aps; from January 2019 to December 2019, Responsible Person according to DK and EU GDP legislation and EU Directives. Establish a new, complete GDP compliant Quality Management System for an international client establishing a new Nordic Sales Affiliate with distribution of Daiichi Sankyo products to the Nordic countries.
  Apply for a WDA to the Danish Medicines Authorities (DKMA approval in December 2019).
  Train staff in basic GDP, write and approve SOP's, establish oversight documents and systems for audit and self-inspections, handling deviations and CAPA, change management and risk Assessments. Establish sufficient quality level for GDP SOP's in order for an approval from the DKMA. Qualification of suppliers, customers and contract-acceptors by audit. Appointed Local Safety Office, providing surveillance of the the Danish GVP legislation. Act as sparring partner to Daiichi Sankyo's international pharmacovigilance team and the EU QPPV.
  Further conduct audits of Logistics Service Providers in DK, Spain and Portugal on behalf of the headquarters Daichii Sankyo Europe, situated in Germany.

- ALK AS; from August 2015 to June 2017, QA support in regard of several GMP compliance projects and inspection readiness, train production staff in GMP and warehouse staff in GDP, support to daily production, workshops etc. within the professional area of allergy vaccines.

Specific GMP consultancy

- Pharmanovia AS; inspection readiness prior to DKMA inspection incl. training staff in behaviour, update relevant documentation, conduct mock audit and be present during authorities inspections.
- Infectopharma GmbH; supporting establishment of Danish Licence for Euphoriant Drugs
- Salfarm Danmark; QA support to veterinary medicinal products; QMS and MAH responsibility. Conduct audit of vet. vaccine manufacturer

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Other long term GDP consultancy

- BHS Logistics AS; Since August 2017 (and on-going), GDP support to deviations and CAPA management, change controls, write SOP's and policies, protocol and reports for temperature mapping of GDP storages and vehicles, conducts risk assessment, audit of sub-contractors (other transport companies), self-inspections, protocols/report for verification of GDP IT systems, risk assessment of transport routes and various GDP subjects, GDP training etc.

- 2care4; Since Nov. 2020 (and on-going), Support to parallel import (PI), GDP/GMP support to various PI tasks and project re. Dispensation from physical reference samples for parallel importers, which succeeded in DKMA accepting PI to import and release with digital samples in a given period.

Main tasks, GxP audits

- GDP approval and routine audits of Importers, Wholesale Distributors and Service Logistic Providers in DK and EU
- GMP approval and routine audits of GMP manufacturers (classic and biotech productions) incl. external QP release
- API audits e.g. chemical and biological API manufacturers in DK and Asia
- 3rd party audits of biological + chemical API manufacturer in DK
- Excipients audits in DK; organic solvents and liquids (ISO 9001 or similar standards)
- Audits of GMP laboratories (analytical, biological, microbiological laboratories) in DK and EU
- Pharmacovigilance audit in Switzerland
- GMP/GDP self-inspections in DK for various GxP companies
- GMP and GDP Mock inspections prior to DKMA approval inspections
- Mock recall inspections
- Participate in GMP/GDP customer audits for Danish clients

Main support to Quality Management Systems, QMS:

- Regain GxP licences after suspension of MIA
- Build a new GxP compliant QMS incl. readiness for GxP inspections
- GAP analysis GMP/GDP prior to authority inspections
- LEAN of QMS e.g. optimize batch documentation
- Update GMP/GDP Quality Management Systems
- Establish policies and overall company procedures within quality, IT, validation, quality risk management, business continuity- and disaster recovery plans, GDPR legislation etc.
- Establish and update SOP's, deviation and CAPA management, change control systems, audit management/control systems, QP-QP agreements, QA agreements, SLA with service providers etc.
- Participate as client part in several DKMA inspections (routine and preapproval inspections)

Projects;

- GxP support to new Stem Cell laboratory incl. facilities/equipment for clean room production.

GMP/GDP Training, workshops and seminars;

- Outsourcing of GMP manufacturing and GMP laboratories (QA/QC/production)
- General GMP/GDP awareness seminars for GxP-companies (improving quality mind-set)
- Basic GDP courses
- Specific GDP courses for wholesalers, transport companies, cleaning companies
- Specific GMP/GDP courses for GMP and IMP Manufactures and for QA organisations
- GMP/GDP workshops within IT, validation, change management, risk assessment, business continuity, disaster recovery, quality risk assessment.
- External teacher at Pharmakon Hillerød e.g. 1 days course in New GDP regulations for transport of medicinal products
- External teacher at Pharmakon Hillerød e.g. 2 days course in quality risk management incl. workshops

PREVIOUS CARRIER

2012 – 2014 Danish Health and Medicines Authority; the inspection department

- Medicines inspector for GMP, GDP and blood banks
- Internal Auditor for 3 laboratories; chemical, microbiology/biology and radioactive laboratories according to DS/EN ISO 17025 standard
- Internal auditor for departments related to inspection and GMP/GDP authorizations according to DS/EN ISO 17020 standard
- Professional Responsible for IT, GDP, narcotic drugs and veterinary drugs incl. interpretation of legalization and education/training of other DKMA employees in the disciplines.
- Responsible for GMP seminars in DKMA inspector team
- Interpretation of and training in the new GDP guideline from 2013
- Quality system: Elaboration of templates, reports and internal SOP's.
- Participation in recruitment procedures
- Sparring partner in quality for DKMA Top Management
- Sparring partner for the GDP team
- Training of new GMP-/GDP-inspectors
- Assigned specialist of training in EU-GMP/GDP subjects at Pharmakon (external training)

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2007 – 2012 Danish Medicines Agency; the inspection department

- Medicines inspector for GMP, GDP, pharmacovigilance, blood banks and relief organizations
- Auditor for inspection departments according to DS/EN ISO 17020 standard
- Auditor for chemical, microbiology/biology and radioactive laboratories (DS/EN ISO 17025)
- Professional responsible for the disciplines pharmacovigilance vet., veterinary drugs, Centralized Authorized Products (CAP)
- Responsible for GMP seminars in the DKMA inspector team
- Responsible for departmental professional GxP seminars
- Participation in EMA GMP working group (IWG) and EMA Pharmacovigilance vet. IWG
- Participation in establishment of Pharmacovigilance training course for EU inspectors
- Responsible for handling sampling and CAP to analysis at EDQM
- Sparring partner in quality for top management
- Sparring partner for several quality projects
- Assigned specialist of training in EU- GMP/GDP subjects at Pharmakon (external training)

2005 – 2007 Novo Nordisk A/S, Project Manager, Local Manufacturing & Sourcing

- Development of new Business Support Organisation incl. development of an IT strategy
- Development of competencies related to Business Strategy and establishment of relevant and related training and competencies
- Quality Support to Affiliate of Aseptic Production (EU and US GMP requirements)in Koriyama, Japan
- GMP training of production staff in Affiliate in Koriyama, Japan
- Quality Coordinator; planning, participation and follow up internal and external audits and inspections from the authorities (EU and US GMP requirements)
- Coordinator for Quality Management Reviews
- Project management of several quality projects; ISO-Train an electronic GMP training system and different LEAN projects
- Implementation of LEAN incl. establish LEAN tools and conduct training sessions

2001 – 2005 Novo Nordisk A/S: Project Manager, Contract & Licence Manufacture

- Project manager; establish licence production for packaging vials in Belarus, 3 month
- Project manager; establish licence production in Cuba; aseptic filling and packaging, 4,5 years
- Quality Support to Affiliate Aseptic production (EU and US GMP requirements) in Koriyama, Japan
- Establishment of an “ERFA group” re. specific Japanese authorities regulations of aseptic and sterile processing
- Quality Responsible for implementing GMP and ISO 9001 in Production Site in Kalundborg
- Coordinator for Quality Management Reviews (DS/EN ISO 9001)
  QA Manager at Scanpharm since May 2020.
- Quality Coordinator; planning, participation and follow up internal + external audits and Authorities inspections (EU and US GMP requirements)

- Establishment of courses in GMP, GDP (EU and US GMP requirements) and ISO 9001 incl. conducting the training
- Establishment of GMP-training matrix for different employees incl. conducting the training

1999 – 2001 Novo Nordisk A/S: Quality Coordinator, API bulk insulin production

- Responsible for implementing the ICH Q7 guideline re. API requirements
- GAP analysis and action plan for implementation of API requirements and follow up
- Optimizing and harmonization of batch documentation in 6 production areas
- Support to API bulk production and in-process laboratory: Review of batch documentation and approval of production steps, Write SOP's, deviations/CAPA management, change control, validations and qualifications (EU and US GMP requirements)
- Establish and train productions staff/academics in API requirements (EU and US GMP requirements)
- Participate in internal audits as GMP specialist (EU and US GMP requirements)
- Coordinate internal audits in the organization (EU and US GMP requirements)

1998 – 1999 Novo Nordisk A/S: Coordinator for aseptic insulin production (finished goods)

- Manager for aseptic cleaning staff and environmental monitoring assistant
- Quality Support in aseptic production and utilities; review of batch documentation and approval, IPC and production trouble shooting, customer complaints, write/update SOP's, change controls, deviations/CAPA management, validation and qualification (EU and US GMP requirements)
- Surveillance and trending of environmental monitoring data from the aseptic production and staff
- GMP training of production staff in aseptic processing and environmental monitoring (EU and US GMP requirements)
- Participation in internal audits and inspections from the authorities as GMP specialist (EU and US GMP requirements)
- Project manager for implementation of LAB system HC*LIMS
- Project manager for implementation of ISO 9001/9002:1994 in Production Site in Kalundborg
- Establishment of Quality Management Review

1994 – 1998 Novo Nordisk A/S: GMP coordinator (insulin packaging department)

- Project manager for implementation of ISO 9001 in Production Site in Kalundborg
- Establish ISO kick-off meetings
- Establish a local ISO steering committee and a local ISO project organization
- Participate in multidisciplinary workshops for harmonization of overall cross functional Novo Nordisk quality policies and procedures according to ISO 9001
- International ISO training of staff from affiliates in South Africa and Japan
- Overall NNAS cross functional training in ISO 9001
- Responsible for reference samples (EU and US GMP requirements)
- Responsible for regular GMP quality meetings in packaging, assembly and stock (EU and US GMP requirements)
- Participate in internal audits and inspections from the authorities as GMP specialist (EU and US GMP requirements)

- Optimization of documentation and QMS according to ISO and GMP requirements (EU and US GMP requirements)
- Establish a standard for Annual Product Review/Product Quality Review and conduct APR/PQR
- Harmonization of batch documentation (EU and US GMP requirements)
- Establish Cross functional quality and professionals GMP meetings in DP productions sites (Kalundborg and Bagsværd)
- Quality support to packaging, assembly and warehouses; responsible for review of batch documentation, write/update SOP's, deviations/CAPA management, change controls, customer complaints (EU and US GMP requirements)
- GMP training of production staff (EU and US GMP requirements)

1994 – 1994 Head Dispenser, Asnæs Pharmacy (4 month)

- Counter expedition in main pharmacy and affiliate

Main Education:

- 2010: Lead Assessor, ISO 17025, DANAK
- 1999: Project manager, Novo Nordisk A/S
- 1997: Certified ISO 9001 Lead Auditor, BSI Training Service
- 1993: M.Sc. Pharm. Copenhagen Pharmacy University

External lectures:	**Title / organizer**
May 2016	Quality Risk Management incl. workshops, Pharmakon, 2 days,
September 2014:	New GDP guideline, Pharmakon, 1 day
September 2013:	New GDP guideline, Pharmakon, 1 day
April & May 2013:	Interpretation and training in new GDP guideline, DMA, 2 days
March 2008:	EU GMP, Pharmakon, 1 day
April 2008	Qualification and validation of equipment, Pharmakon, 2 days

Network groups:

From 2015-2019:	Chairman for new established QA network group, Association of Industrial Pharma- and Medico Forum, IFF
2001 – 2003:	Chairman for Japan Quality Network group, Novo Nordisk AS

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Trusts:

2019 - 2021	Vice Chairman of the Board, Association of Industrial Pharma- and Medico Forum, IFF
From 2019:	Chairman of the Board, “Skærby Strand Vejlaug” (in Danish)
From 2018:	Member of the Board, ”Buske Nord Grundejerforening” (In Danish)
From 2015:	Member of the Board, Association of Industrial Pharma- and Medico Forum, IFF
From 2014:	Founder and member of the Board, GxP-Pharma Support AS
From 2006:	Chairman of the Board, Nomas AS
1997 – 2014:	Chairman of the Board, “Nørre Hvalsø Bylaug” (in Danish)